JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(MEDICAL RESEARCH & ETHICS COMMITTEE)
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA
Kompleks Institut Kesihatan Negara (NIH)
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Ref. : KKM/NIHSEC/P21-903(12)
Date : **9-July-2021**

KAMARUDIN BIN AHMAD
HOSPITAL MIRI

Dear Dato'/ Dr/ Sir/ Madam,

LETTER OF ETHICAL APPROVAL:

NMRR-21-767-59240 (IIR)
EFFECTIVENESS OF PHARMACY INTEGRATED COMMUNITY CARE (PICC) IMPROVING HEMOGLOBIN A1C (HBA1C) AND KNOWLEDGE IN DIABETES MELLITUS (DM) EDUCATION PROGRAM

This letter is made in reference to the matter above.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has provided ethical approval for this study. Please take note that all records and data are to be kept strictly **CONFIDENTIAL** and can only be used for the purpose of this study. All precautions are be taken to maintain data confidentiality. Permission from the District Health Officer / Hospital Administrator/ Hospital Director and all relevant heads of departments /units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations including the Access to the Biological and Benefit Sharing Act 2017.

3. The investigators and sites involved in this study are:

Klinik Kesihatan Bandar Miri
Kamarudin Bin Ahmad (Principal / Coordinating Investigator)
Chai Min Choo

Klinik Kesihatan Jalan Masjid Kuching, Sarawak
Associate Professor Dr. Lawrence Anak Anchah
Izzul Syazwan Bin Shuib
Juliet Lau Lu Lin
Lim Su Ee

Klinik Kesihatan Jalan Oya
Chang Poh Yin

Klinik Kesihatan Kapit
Ngu Chiew Pin

Klinik Kesihatan Paloh
Kho Boon Yan

.../3-

Ref : KKM/NIHSEC/P21-903(12)

Klinik Kesihatan Pusa
Kiu Kuan Cia

Klinik Kesihatan Sarikei
Amy Ting Siew Shin

Klinik Kesihatan Siburan
Kenny Goh Wei Chuan

Klinik Kesihatan Sri Aman
Mary Wong Siew King

4. The following study documents have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Cover letter to MREC (Version 3, dated 07-07-2021)
2. Declaration of Conflict of Interest (COI) (Version 2, dated 20-05-2021)
3. Protocol (Version 3, dated 07-07-2021)
4. English: Patient Information Sheet/ Informed Consent Form (Version 3, dated 07-07-2021)
5. Malay: Patient Information Sheet/ Informed Consent Form (Version 3, dated 07-07-2021)
6. Questionnaire (Version 2, dated 20-05-2021)
7. Data Collection Form (Version 2, dated 20-05-2021)
8. Follow-up Review Report (Version 1, dated 07-07-2021)
9. IA-HOD-IA, CV and GCP Certification of:
    - Kamarudin Bin Ahmad
    - Associate Professor Dr. Lawrence Anak Anchah
10. IA-HOD-IA and CV of:
    - Chai Min Choo
    - Izzul Syazwan Bin Shuib
    - Juliet Lau Lu Lin
    - Lim Su Ee
    - Chang Poh Yin
    - Ngu Chiew Pin
    - Kho Boon Yan
    - Kiu Kuan Cia
    - Amy Ting Siew Shin
    - Kenny Goh Wei Chuan
    - Mary Wong Siew King

5. Please note that the approval is valid until **08-July-2022**.The following are to be reported upon receiving ethical approval. Required forms can be obtained from the National Medical Research Registry (NMRR) website.

i. **Continuing Review Form** has to be submitted to MREC within 2 months (60 days) prior to the expiry of ethical approval.
ii. **Study Final Report** upon study completion to the MREC.
iii. Ethical approval is required in the case of **amendments/ changes** to the **study documents/ study sites/ study team**. MREC reserves the right to withdraw ethical approval if changes to study documents are not completely declared.
iv. **Applicable for Clinical interventional Studies only:** Report occurrences of **all Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reaction (SUSARs)** and **Protocol Deviation/Violation** at all MREC approved sites to MREC. SAEs are to be reported within 15 calendar days from awareness of event by investigator. Initial report of SUSARs are

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to be reported as soon as possible but not later than 7 calendar days from awareness of event by investigator, followed by a complete report within 8 additional calendar days.

6. There will be **94 subjects/ patients/ respondents** targeted to be enrolled in this study within Malaysia.

7. Please take note that the reference number of this letter must be stated in all future correspondence related to this study to facilitate the administrative processes.

Project Sites:
KLINIK KESIHATAN BANDAR MIRI
KLINIK KESIHATAN JALAN MASJID KUCHING, SARAWAK
KLINIK KESIHATAN JALAN OYA
KLINIK KESIHATAN KAPIT
KLINIK KESIHATAN PALOH|DARO
KLINIK KESIHATAN PUSA
KLINIK KESIHATAN SARIKEI
KLINIK KESIHATAN SIBURAN
KLINIK KESIHATAN SRI AMAN

Decision by Medical Research & Ethics Committee:
(√) Approved
( ) Disapproved

Date of Approval : **9-July-2021**

.....
DR. HJH SALINA BINTI ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
(MMC No: 27117)

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Study Protocol

Effectiveness of Pharmacy Integrated Community Care (PICC) improving Hemoglobin A1c (HBA1C) and Knowledge in diabetes mellitus (DM) education program

Protocol number, version number and date:
PICC0003, Version 3.0 dated 7 July 2021

Name and Institution of Principal investigator:
Kamarudin Bin Ahmad, Hospital Miri
Dr Lawrence Anchah, Medical Faculty UNIMAS

Name and Institution of Co-Investigators:

Name	Working Institution	Study Site	District
Kamarudin Bin Ahmad	Hospital Miri	Klinik Kesihatan Bandar Miri	Miri
Dr Lawrence Anchah	Medical Faculty UNIMAS	Klinik Kesihatan Jalan Masjid Kuching	Kuching
Lim Su Ee	Bahagian Perkhidmatan Farmasi, Jabatan Kesihatan Negeri Sarawak	Klinik Kesihatan Jalan Masjid Kuching	Kuching
Izzul Syazwan Bin Syuib	Cawangan Penguatkuasa Farmasi, Jabatan Kesihatan Negeri Sarawak	Klinik Kesihatan Jalan Masjid Kuching	Kuching
Amy Ting Siew Shin	Pejabat Kesihatan Bahagian Sarikei	Klinik Kesihatan Sarikei	Sarikei
Chai Min Choo	Klinik Kesihatan Tudan	Klinik Kesihatan Bandar Miri	Miri
Chang Poh Yin	Klinik Kesihatan Jalan Oya	Klinik Kesihatan Jalan Oya	Sibu
Juliet Lau Lu Lin	Klinik Kesihatan Jalan Masjid	Klinik Kesihatan Jalan Masjid Kuching	Kuching
Kenny Goh Wei Chuan	Klinik Kesihatan Siburan	Klinik Kesihatan Siburan	Serian
Kho Boon Yan	Klinik Kesihatan Daro	Klinik Kesihatan Daro	Mukah

Kiu Kuan Chia	Klinik Kesihatan Pusa	Klinik Kesihatan Pusa	Betong
Mary Wong Siew King	Klinik Kesihatan Sri Aman	Klinik Kesihatan Sri Aman	Sri Aman
Ngu Chiew Pin	Klinik Kesihatan Kapit	Klinik Kesihatan Kapit	Kapit

Name and address of Sponsor:
Using departmental operating budget, Jabatan Kesihatan Negeri Sarawak, Kementerian Kesihatan Malaysia

Study site/s:

Klinik Kesihatan Bandar Miri

Klinik Kesihatan Jalan Masjid Kuching

Klinik Kesihatan Sarikei

Klinik Kesihatan Jalan Oya

Klinik Kesihatan Siburan

Klinik Kesihatan Daro

Klinik Kesihatan Pusa

Klinik Kesihatan Sri Aman

Klinik Kesihatan Kapit

Contents

List of Abbreviations

AKYM	Ambassadors Know Your Medicine (AKYM)
CONSORT	Consolidated Standards of Reporting Trials
DM	diabetes mellitus
DMTAC	diabetes medication therapy adherence clinic (DMTAC)
GBI	group-based intervention (GBI)
HBA1C	Hemoglobin A1c
IMP	investigation of the medicinal product
MREC	Medical Research and Ethics Committee
NCDs	non-communicable diseases
NHMS	National Health Morbidity Survey
NPAN	National Plan of Action for Nutrition (NPAN III)
PhIS	Pharmacy Information System
PICC	Pharmacy Integrated Community Care
SAE	serious adverse event
SGBI	Structured group-based intervention
SPIRIT	Standard Protocol Items: Recommendations for Interventional
SUSAR	serious adverse reaction
T2DM	Type 2 diabetes mellitus
WHO	World Health Organization

Research Synopsis

Study title	Effectiveness of Pharmacy Integrated Community Care (PICC) improving Hemoglobin A1c (HBA1C) and Knowledge in diabetes mellitus (DM) education program
Study Population	The study population will be local people living in Sarawak from multiple racial backgrounds with underlying type 2 diabetes mellitus (T2DM). We recruit patients with underlying T2DM mellitus who obtain medication at the primary Government Health Clinic in each district.
Study Design	The study's design will be a prospective, multicenter and parallel-design single blind randomised controlled with two treatment groups. The trial evaluates a PICC's effectiveness in improving HBA1C involving four-session structured group-based intervention (SGBI) of a two to three-hour pharmacist-led program with follow up evaluations. The control arm will have the same syllabus without SGBI.
General Objective	1. To describe and critically appraised DM education studies. 2. To examine the program's effectiveness versus control in improving medication adherence with underlying T2DM in the Sarawak State of Malaysia.
Specific Objectives	1. To measure the effectiveness of PICC in improving HbA1C, fasting blood glucose and understanding 2. To investigate the sustainability of the program.
Study endpoints/outcomes	Primary outcome: HbA1C will be the primary outcome. We will collect this by using a point of care test. Secondary outcome: Investigating knowledge and understanding of DM medication management will be evaluated using the quizzes in the PICC program.
Sample Size	A previous study has shown a standard deviation of 1.5. Suppose the true difference between the experimental and control means is 1, 36 experimental subjects and 36 control subjects with a probability (power) of 0.8. By estimating 30% dropout or incomplete data, a minimum sample size of 94 (47 for each group).
Study Duration	1 August to 31 December 2021.

RESEARCH PROPOSAL FOR HIGHER DEGREE PROGRAMMES
BY: KAMARUDIN BIN AHMAD

1. Field of Research

Clinical Trials

2. Topic of Research

Effectiveness of Pharmacy Integrated Community Care (PICC) improving Hemoglobin A1c (HBA1C) and Knowledge in diabetes mellitus (DM) education program

3. Background and Significance

3.1 Current situation globally on DM

What happens globally on DM? How does it affect people?

According to WHO global statistics on diabetes mellitus (DM), the prevalence among adults 18 years of age has risen from 4.7% in 1980 to 8.5% in 2014.1 It is also worrying that the majority of DM has been growing more rapidly in the middle- and low-middle and low-income countries such as in Malaysia (1).

T2DM continues to increase in prevalence, incidence and is a leading cause of human suffering and death. Despite significant investments in clinical care, research, and public health interventions, there appears to be no sign of a reduction in the rate of increase. Certain regions of the world, such as Western Europe and island states in the Pacific, are experiencing a disproportionately high burden (2).

WHO estimates that the number of people with diabetes in the Western Pacific Region may reach 150 million by 2025 appear by no means unrealistic and may even be conservative (3). Globally, about 1 in 11 adults have DM (90% have T2DM), and Asia is the epicentre of this global T2DM epidemic (4).

Given its global influence, it is essential to break the vicious cycle of DM by getting DM over generations by implementing effective strategies to prevent gestational DM. Among patients with T2DM, cardiovascular complications are the leading cause of morbidity and mortality, and kidney complications are highly prevalent in patients in Asia with DM (4-6).

Poor medication adherence is a public health problem that incurs a considerable financial cost (7). Poor adherence may reduce the effectiveness of treatment. A recent systematic review found that nonadherence to oral antidiabetic medication ranged from 36% to 93% in patients remaining on treatment for at least six months (8).

The burden of T2DM and its complications is substantial and escalating and poses a substantial economic burden. Significant challenges include unawareness, undiagnosed cases, the coexistence of T2DM with tuberculosis and other infections, the high costof diagnostic tests, insulin, and drugs, and the scarcity of trained health workers (9).

What causes it increase in DM prevalance?

The major driving factors of the global T2DM epidemic include overweight and obesity, sedentary lifestyle and increased consumption of unhealthy diets containing high levels of red meat and processed meat, refined grains and sugar-sweetened beverages (4). The appearance of T2DM, in association with obesity, in children is a cause for particular concern. The easy availability of fast foods and a sedentary lifestyle, associated with lack of physical play, television and

computers, and mechanisation, have rapidly altered the behaviour patterns of the urbanised young in many of Asia's megacities (3).

The overall empirical evidence suggested that higher socio-economic status, more excellent dietary knowledge, and higher self-efficacy and empowerment improve glycaemic control among patients with diabetes. Higher socio-economic statuses and good diabetes-related knowledge were more likely to have better glycaemic control due to more accessible access to resources and better compliance to diabetes self-management (10).

What should we do to fight DM?

This epidemic will require an urgent and unwavering commitment to aggressive solutions at national levels with public policies, public health funding, and economic incentives for local communities to start diabetes prevention programs. Healthy eating options need to be subsidized, and unhealthy foods need to be taxed or otherwise disincentivised. Healthcare organisations and individual healthcare providers from multiple disciplines (doctors, nurses, pharmacists, dieticians, and diabetes educators) must be given time and resources to collaborate as they educate and care for individuals and groups of patients. Unless urgent measures are instituted to reduce unhealthy eating, sedentary lifestyles, rapid urbanisation, and other factors related to economic development, the burden of diabetes is expected to continue rising (2).

Efforts to contain this epidemic should include increasing awareness, effective primary prevention, the use of allied health professionals for prevention and education, improving the standard of care, using mobile phones and telemedicine to deliver health messages, and regulation to promote healthy foods and curb unhealthy oils and sugary drinks (9)

In addition, with higher self-efficacy and empowerment, patients with DM are more motivated to use a dynamic approach to acquire dietary knowledge and actively seeking health-promoting behaviours to enhance diabetes self-management. Further research must be conducted to comprehend the drivers of this epidemic to improve prevention strategies for this public health issue. In addition, greater emphasis needs to be placed on implementing lifestyle changes on a societal level to stem the tide of the epidemic. It is necessary to implementation accessible multicultural educational initiatives for the general public (10).

3.3 Strategy reducing DM

Major clinical trials have demonstrated that diet and lifestyle modifications are effective in preventing T2DM in high-risk individuals. T2DM management strategies, including lifestyle modifications, social support and ensuring medication adherence, are vital in reducing DM complications (4, 9, 11, 12).

Higher socio-economic status, more excellent dietary knowledge, and higher self-efficacy and empowerment are also shown to improve glycaemic control among patients with DM (10). Future public health policy must be geared towards increasing the capability of dealing with the rising incidence of diabetes and implementing primary prevention. There is a need to prevent lifestyle-related diseases by emphasising patient empowerment (10).

Having a good or poor knowledge level on diabetes medication does not guarantee their health-seeking practice of medication adherence. Therefore, further focus on providing patient education and support in health care clinics to ensure that they have sufficient awareness of diabetes and the practice of medication adherence in order to prevent the early development of diabetes complications (13).

Lay-led, group-based self-management interventions were revealed to have significant effects on improvement of HbA1c levels, self-efficacy, reduce costs, reduce complications, and improve the quality of life for patients (14, 15). Hence,

an intervention could motivate them intrinsically toward self-management behaviours to manage their conditions better and for a more extended sustained period. Such interventions were also shown to improve their confidence to manage their condition and reduce its complications, to benefit them clinically.

3.4 Literature Review

The current situation in Malaysia

In the 2011 National Health and Morbidity Survey (NHMS) IV, of those already diagnosed with diabetes, an estimated 1.1 million received treatment at public health care facilities (16). Of those receiving public-based health care, an estimated 70% attended primary care clinics, whereas the remaining received treatment and follow-up at public hospitals (16). The prevalence of DM rose in 2015 to 17.5% (9).

Overall, we estimated the total cost of diabetes as RM2.04 billion per year for the year 2011 (both public and private sector). Of this, RM1.40 billion per year was incurred by the government. Despite some limitations, we believe our study provides insight into the actual cost of diabetes to the country. The high cost to the nation highlights the importance of primary and secondary prevention (17).

.Medical officers and physicians mainly deliver public hospital-based diabetes care comprehensively within general medicine outpatient clinics. Consultations are focused on optimising glycemic control with antihyperglycemic therapies (alone or in combination) and reinforcing lifestyle intervention while specifically addressing cardiovascular risk reduction (18). Multidisciplinary care is available in tertiary and primary care settings to integrate pharmacotherapy, diet, and lifestyle changes (19).

The Malaysians had a moderate medication adherence level, whereas they were nonadherent to blood glucose testing (20). Emphasis on self-care activities and medication adherence is relevant to improving type-2 DM (T2DM). Results of this study indicated that low medication adherence was related to a larger BMI and a poorer HbA1c. Patients had the highest mean score for general diet on the SDSCA. It was also revealed that the patients had better self-care behaviour in the

general diet than blood glucose testing. Primary health care providers should provide adequate counselling for adults with T2DM (20)

A study in Malaysia described how patients are informed and influenced by several sources: family members, friends and peers, health care providers, books and electronic materials (21). Studies have indicated that lower education is associated with more inadequate diabetes knowledge (22, 23). However, diabetes empowerment scores were high among T2DM patients who had above secondary education level, diabetes education exposure, no ischemic heart disease status and lower HbA1c; thus, all the diabetes patients should be educated and empower on self-care for long-term diabetes management (24).

Strategies reducing DM in Malaysia

Various action plans and programs have already been formulated and implemented in the country. Reducing non-communicable diseases (NCDs) (including diabetes) is one of the three objectives of the third edition of the National Plan of Action for Nutrition (NPAN III) of Malaysia (2016–2025)(25) and The National Strategic Plan for Non-Communicable Disease (2010–2014) is a medium-term strategic plan to strengthen further the cardiovascular diseases and diabetes prevention and control program in Malaysia (26).

Despite the various action plans outlined above, adherence plays an essential factor in DM medication therapy. A recent national survey in Malaysia revealed that 73.1% of Malaysians did not adhere to the medications that they are prescribed (27). The only local literature supporting the positive association between patient satisfaction and medication adherence in T2DM patients was a study amongst patients attending the diabetes medication therapy adherence clinic (DMTAC) run by pharmacists (28). DMTAC is a structured DM education program to help the patient to cope with various need-to-know information on DM

so that they can do self-care. The patients were satisfied with the DMTAC service; however, the majority of the patients not adhered to their medications (29).

In order to increase health literacy and self-care practices, the Know Your Medicine Campaign was launch to create awareness for Malaysians (27). A survey was conducted; however, approximately half of the respondents were not aware of the KYM campaign with the urban population was found more knowledgeable about the appropriate use of medicines (27). Efforts to disseminate the information, especially among the rural population, should be strengthened through adopting the most accessible media channels (30).

A recent trial on 'Know Your Medicine – Take it for Health' (MEDIHEALTH) in Malaysia tested the effectiveness of structure group-based intervention (SGBI) (31). The targeted well-structured DM education under that program proved an increase in medication adherence, specifically in DM (32). Thus, DM education might be the key to the success of DM control. Both pharmacist-led and physician-led interventions in improving medication adherence were found to be effective. Hence, it is suggested that a multifaceted approach with the involvement of different healthcare professionals should be encouraged to synergise the strengths of each profession and further enhance the effectiveness of interventions (33).

Soon after MEDIHEALTH, the Ministry of Health Malaysia endorses Pharmacy Integrated Community Care (PICC) which is an innovation introduced by the Pharmaceutical Services Division, Terengganu State Health Department. The programme aims to optimise the treatment of patients' diabetes in the community. In 2020, this initiative improved and expanded nationwide to enable people to benefit from this initiative. PICC includes medication management activities, healthy lifestyle practices and a balanced diet. PICC implemented through pharmacy officers' collaboration; Ambassadors Know Your Medicine (AKYM), dietetic officers, nutrition science officers, nurses, assistant medical officers and

physiotherapists. AKYM came from an activist that promotes the Know Your Medicine Campaign.

PICC creating support groups for DM patients that help increase motivation in controlling diabetes, recognising and understanding diabetes, self-management and provide exposure to nutrition and a healthy lifestyle to people with diabetes.

PICC participants consist of diabetics in the community. A pharmacist or AKYM will select the participant for this program. Participants must agree to attend at least three of the four PICC sessions. Patients with uncontrolled mental illness excluded from the program.

How GBI improved DM in Malaysia and other countries?

Zare et al. (2020) conduct a systematic review of a self-care intervention study to assess the effectiveness of diabetic self-management and the appropriateness of the used theories and models. Interventions that utilise self-efficacy, social support, or empowerment constructs in addition to intra-individual constructs have been shown more effective which delivered by using GBI (15).

GBI was revealed to significantly affect HbA1c levels, self-efficacy, and frequency of emergency visits (14). Consistent with trials on GBI in Malaysia (32, 34, 35), various studies show an intervention could motivate them intrinsically toward self-management, improved negative emotions and health-coping behaviours (36-38). Such interventions were also shown to improve their confidence to manage their condition and reduce its complications, to benefit them clinically.

Few studies have been done regarding the effects of GBI on the frequency of emergency visits. Reductions in emergency visits can also reduce the health care cost, which can reduce the overall rising cost related to treating complications related to T2DM (14).

What are the gaps in GBI studies?

Trials on GBI in Malaysia focus on medication adherence and self-care practices (32, 34, 35). Other studies of diabetes in Malaysia have suggested that patients have inadequate knowledge of diabetes and a shortage of professional educators such as dieticians or diabetes educators (22, 35, 39). One study reported some challenges that diabetes educators face in effectively helping patients with their self-care. Given limited resources, creative approaches such as brief, structured education may help address knowledge gaps and improve diabetes self-care (35).

Healthcare professionals can assist patients in setting diabetes-related health goals that are clinically appropriate and acceptable to the patient. By considering the desire for more knowledge, health professionals provide patients with specific, practical counselling on diet, exercise, and medications. Existing resource limitations within the healthcare system, such as inadequate access to dieticians, necessitate creative solutions. While keeping in mind common diabetes self-care barriers and facilitators, health professionals also recognise that these may vary across and within ethnic groups. Healthcare providers can understand the barriers and facilitators most relevant to a specific patient (40).

There is a gap in the practice of diabetes educators and the need for change in the approach to service delivery and the healthcare organisation as a whole. Conducting action research or participatory research would help implement patient-centred care intervention, as it would empower the stakeholders, facilitate their interest and participation and simultaneously increase their sense of responsibility and ownership of the intervention (41). This would also reduce the possibility of resistance to implementing changes in the healthcare system (42).

Education is a prerequisite for effective diabetes management and will remain a fundamental part of treating the disease for the foreseeable future; therefore, for both ethical and practical reasons, it remains of great importance to providing everyone with diabetes education that is culturally and socially appropriate for their

situation (36). However, there were many variations in design regarding the delivery of diabetes education by peer leaders and the way support was given. GBI should follow a set of evidence-based guidelines to enable the standardisation of interventions and allow its effects to be transferable across cultural barriers (14). PICC could serve a function in an effort towards standardisation; however, improving the knowledge in DM patients is yet to be proven.

3.4 Research Questions

How effective is PICC?

Malaysia has developed various action plans to curb DM that consist of nutrition, obesity and non-communicable disease. Despite the various action plans, it would be essential to ask why the prevalence of diabetes and risk factors remains at high levels (43). It is essential to scrutinise the implementation of these plans and identify the reasons for the shortfalls and the challenges faced. The main challenges identified in this review included a lack of intersectoral and multi-stakeholder coordination, lack of human resource capacity to deliver the identified programs and lack of monitoring and evaluation. These shortcomings require transformation when implementing the next phase of national plans. This study will evaluate the effectiveness of PICC as one of the national initiatives to curb DM.

The PICC trial will explore the program's effectiveness and find gaps to improve patient knowledge in DM, self-care practices and glycaemic control. Conducting PICC trials would help implement patient-centred care intervention, which would empower the stakeholders, facilitate their interest and participation and simultaneously increase their sense of responsibility and ownership of the intervention. Hence, this would also reduce the possibility of resistance to implementing changes in the healthcare system.

How effective PICC improve DM knowledge?

Studies found limited knowledge to be prevalent in patients with T2DM, which means that most patients cannot use their abilities to find fully understand, reflect and apply information to optimally manage their disease (44, 45). We need strategies to improve DM knowledge. Given limited resources, creative approaches such as PICC may help address knowledge gaps and improve diabetes self-care.

Is there a strong association between DM Knowledge and HbA1C?

Management self-efficacy and other patient characteristics found no evidence to suggest diabetes knowledge is associated with blood glucose control, a result consistent with that found by Coates (46). However, this lack of association is inconsistent with several studies considering the impact of diabetes knowledge on glycaemic control. For example, others have demonstrated that higher knowledge is associated with higher control in other populations (47-49), whereas McPherson et al. (2008) showed (50) that diabetes knowledge was inversely associated with glycemic control (51); thus, the discrepancies require further investigation.

Theoretical Framework

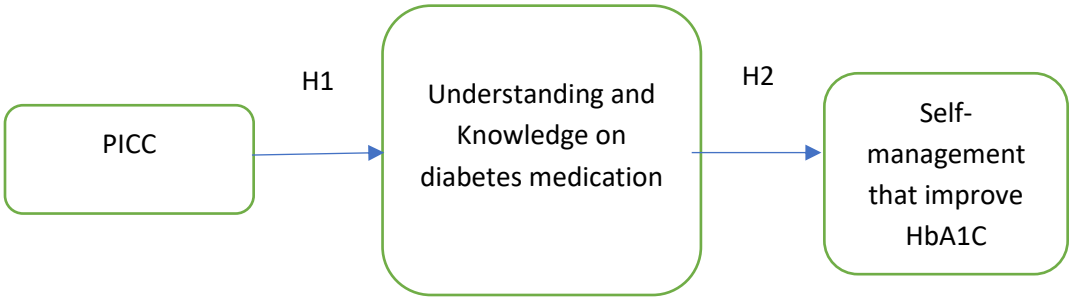


Figure 1: Conceptual framework of the PICC trial.

Hypotheses or research questions based on the conceptual framework:

H1: Is there a significant difference in knowledge on diabetes medication between the PICC group compared to the control group?

H2: Is there a significant difference in reduction of HbA1C between the PICC group and the control group?

3.5 General Objectives

(a) Systematic review on DM knowledge study in Malaysia

Many approaches improving diabetic knowledge and HbA1C; however, there is no answer to which is the best or goal standard in Malaysia. A systematic review helps uncover the gaps and highlights the most feasible and practical technique for a non-pharmacological approach in DM therapy.

(b) Trials on PICC program

Recent trials concluded that GBI employing self-management education for T2DM patients improves medication adherence and glycaemic control among Malay T2DM patients. These effects were mediated by an improvement in knowledge about medications and perceived behavioural control on medication adherence.

However, intervention is a culturally sensitive intervention designed for Malay T2DM in Sarawak (31).

Hence, the present study aimed to bridge the gap in the literature by examining the effectiveness of PICC on improving HbA1C, fasting blood glucose and understanding of the program to the multiracial in Sarawak.

(c) Qualitative survey on the PICC program

PICC is a DM teaching program that gives awareness to the participants and also helps them to incorporate appropriate lifestyles and habits in the long run. This initiative implements the Ministry of Health Malaysia; however, no studies available to evaluate the effectiveness and explore participants perceptions towards the program.

4. Specific objectives

The first part will deal with a systematic review of diabetic education in Malaysia. The aim will be to describe and critically appraised DM education studies.

The second part will deal with a trial on the PICC program among DM patients in Sarawak. The aim will be to examine the program's effectiveness versus control in improving medication adherence with underlying T2DM in the Sarawak State of Malaysia. The specific objectives of this study are:

a) to measure the effectiveness of PICC in improving HbA1C, fasting blood glucose and understanding

b) to investigate the sustainability of the program.

The third part will explore the satisfaction of joining the PICC program using a qualitative survey approach. The aim is to dive into the issues on context, implementation, mechanism and effectiveness.

5. Methods

Part 1: A Systematic Review on DM education in Malaysia

5.1 Search Strategy

Metasearch of online literature will be conducted on electronic databases such as Pubmed, MEDLINE, EMBASE and other specialised journals (e.g. Journal of Diabetes and its Complications, International Journal of Diabetes and Clinical Research, and Journal of Diabetes). Unpublished trials will be identified by contacting the researchers.

5.2 Selection Criteria

All observational studies on the DM education program in Malaysia will be considered for inclusion.

5.3 Data Extraction and Analysis

All relevant data will be extracted using a standardised form. I will independently extract the data from the selected studies, and my supervisor will cross-validate at random the data extracted. The following data will be extracted: study identification, types of study, DM education approach, description of the subject, findings and conclusions.

Part II: PICC Trials

Study Visits and Procedures

Study Design

The study's design will be a prospective, multicenter and parallel-design single-blind, randomised controlled trial with two treatment groups. The protocol is written following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist. The trial evaluates a PICC's effectiveness in improving HBA1C that involves four sessions of SGBI of a two to three hours pharmacist-led program with follow up evaluations, while the control arm will give the same syllabus without SGBI. The trial period will be from 1 September to 31 December 2021.

Study Population and Setting

The study population will be local people living in Sarawak from multiple racial backgrounds with underlying T2DM. We recruit patients with underlying T2DM who obtain medication at the primary Government Health Clinic in each district and randomly assigned them to the treatment group PICC or the control group. The primary outcome of this study is HbA1C levels. The secondary outcomes are knowledge of the PICC Program.

Sample size

This study involved a continuous response variable from control and experimental subjects with one control per experimental subject. In a previous study (31), each subject group's response was normally distributed with a standard deviation of 1.5. If the true difference between the experimental and control means is 1, 36 experimental subjects and 36 control subjects would be required to reject the null hypothesis that the population means of the experimental and control groups are equal, with a probability (power) of 0.8. By estimating 30% dropout or incomplete

data, a minimum sample size of 94 (47 for each group) was pre-determined, as shown in Figure 2.

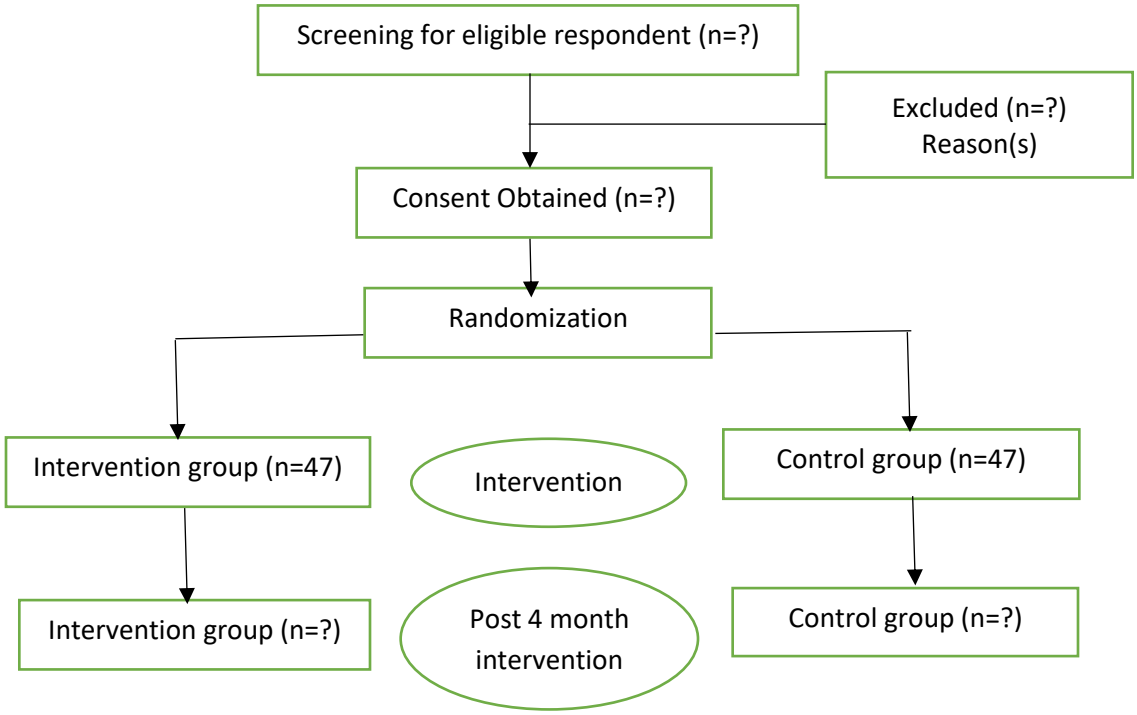


Figure 2. Trial Flow accordance to Consolidated Standards of Reporting Trials (CONSORT)

Inclusion Criteria

A computer-generated list of participants will be allocated to the control and intervention groups (explained further in the randomisation section), as shown in Figure 2. The participants were recruited during their routine clinic visits at a government clinic that provides primary care in each division of Sarawak. Participants with T2DM were included if they:

1. were non-pregnant adults >18 years of age regardless of gender or ethnicity;
2. spoke and understood Bahasa Malaysia

3. had a medical record showing haemoglobin A1c test (HbA1c) level of ≥6.3% (45 mmol/mol) and fasting plasma glucose test (FPG) ≥7.0 mmol/L
4. Patients also need to be able to provide informed consent to participate in the study

Exclusion Criteria

Participants were excluded if they could not answer the quizzes independently or had a hearing or vision impairment. Patients unable to read, write and speak Malay, medically unstable or unable to provide informed consent will be excluded. Patients who are currently attending intensive psychological treatment, hospitalised and participating in other studies will also be excluded from the study.

Extraneous Variable/ Confounding Variables

Several extraneous variables would affect the outcome of this study based on the literature. A review classified the contributing factors of adhering to diabetic medications into five dimensions, namely (1) patient-related, (2) condition-related, (3) socioeconomic, (4) health system-related and (5) therapy-related (52). Furthermore, a more recent review (53) on the factors associated with diabetes medication adherence are categorized into (1) patient factors, (2) prescription factors and (3) prescriber factors.

Hence, extraneous variables included in this study will be (1) route of administration, oral only or oral and insulin injection; (2) numbers of medications, one or more than one (54); (3) frequency of the medications, a once-daily dose or more frequent (55); (4) age; (5) gender; (6) highest education level; (7) monthly household income; (8) employment status; (9) having complications; (10) taking traditional complementary and alternative medicines; (11) residential area, urban or rural; (12) living condition, having social support or stay individually; (13)

undergone diabetic education by the diabetic nurse; (14) enrolled with diabetic MTAC.

Recruitment

Prospective and eligible respondents are recruited consecutively from primary health clinics from nine divisions during their routine scheduled visits before intervention from 1st September to 30th September 2021. A sampling frame acquired from the T2DM patient's list visits the clinic from 1st August to 31st August 2021. The list generated from Pharmacy Information System (PhIS) through prescriptions containing DM medication. Information obtained through prescription screening includes the diagnosis and medications of the patients, name and age. Potential subjects introduced to PICC and recruited for appointment into the program. Approximately one month before the actual study, from 1st – 30th September 2021, will be the screening phase to identify potential respondents. Those who agree to participate will be informed about the program and asked to choose a date during the campaign to attend the program. After choosing the date they prefer, their name will be recorded in the “List of Participants” with a specific code assigned. Notably, patients are not informed of their group assignment and thus are not aware of the differences between the intervention group and the control group. Besides, none of the recruiters who are the pharmacist staff at both health clinics is aware of subsequent treatment allocation throughout the recruitment stage to ensure allocation concealment. All research materials that contain patients’ information will be coded and kept by the principal investigator to maintain the confidentiality of respondents.

Withdrawal Criteria

Participants can choose to withdraw at any time. Participants may be withdrawn if the research team deems that it is detrimental or risky for them to continue;

arrangements will be made for their future care. Withdrawn participants will not be replaced and will be included in the intention-to-treat analysis.

Although subjects may withdraw from the study at any time and for any reason (or may be withdrawn at the Investigator's discretion), subject withdrawal should be avoided as much as reasonably possible. In any case, appropriate follow-up for endpoints should be continued. Subjects who prematurely discontinue are not to be replaced. For subjects considered lost to follow-up, the case report form (CRF) must be completed up to the last visit performed.

If the researcher found that a participant is no longer eligible or suitable for this study and decide to terminate the participant, or a participant decides to withdraw from this study, the following steps of subject withdrawal will be executed.

The principal investigator will ask the participant who is withdrawing or terminated whether the participant intends to provide subsequent follow-up and further data collection after withdrawal or termination from the study's interventional portion. If the participant agrees to continue with subsequent follow-up and data collection, a new informed consent form for limited participation in this study should be obtained. If the participant does not agree to continue with subsequent follow-up and data collection, no medical records or other confidential records requiring informed consent will be accessed by any investigator of this study. Meanwhile, only the data collected before the participant's withdrawal or termination can be accessed, reviewed and remained as part of the study database. Notably, such data should not be removed and should be included for data analysis to avoid a situation called "informative censoring", which could undermine this study's validity. Data analysis techniques, namely intention-to-treat analysis or data imputation, will be performed to overcome the participants' withdrawal or termination. Lastly, the timing and reason for the withdrawal or termination of any participant will be reported by the principal investigator.

Randomisation and Blinding

The Sarawak Pharmacy Service Division be appointed to carry out the simple randomisation. The “List of Participants” will be handed over to one appointed officers to carry out the randomisation. The randomisation will be conducted using an online randomisation program at http://www.graphpad.com/quickcalcs/index.cfm as recommended by (56). After that, the participants’ list with their code and group assignment will be kept by the Sarawak Pharmacy Service Division without informing any researchers, facilitators and respondents to ensure three parties' blinding about the treatment allocation. Participants are given appointment dates, while facilitators are only informed to do either the intervention activity or the control activity when the participants arrived.

For the blinding of researchers, it will be continued towards the stage of publication. During the post-intervention follow up, the researchers still are blinded by the participants' allocation, as the Sarawak Pharmacy Service Division keeps the participant list with group allocation. None of the instruments distributed to the participants will disclose their name and group assignment to assure the blinding among researchers who do the data analyses. Only after this study's results are published, the blinding or the codes will be broken through the return of the participants’ list to the principal investigator. The Sarawak Pharmacy Service Division will maintain the randomisation codes throughout the study without disclosing them to the researchers or the participants.

No breaking code procedure is necessary for this study as the intervention of this study is educational and does not involve the investigation of medicinal products (IMP). Thus, the risk of suspected unexpected severe adverse reaction (SUSAR) or serious adverse event (SAE) would be a minimum or none. However, should any SAE or SUSAR happen during the study, the principal investigator will report to the MREC and the physicians of the health clinic to rule out the possibility of such condition is due to this study before proceeding breaking the code.

Intervention Design (study visit and Procedure)

The structured group-based intervention (SGBI) adopted by this study was formulated and employed by the Pharmaceutical Services Division of Sarawak State Health Department in promoting medication adherence among T2DM Malay patients. The official name of the intervention is “Pharmacy Integrated Community Care”. This SGBI employed an understanding self-care approach. It was specifically designed to complement the individual approach in improving understanding of T2DM medication management because group-based intervention (GBI) can engage more patients at once and build the fundamental capability of patients to adhere to prescribed medications within a shorter period as compared to the individual approach. Nevertheless, SGBI has numerous irreplaceable benefits (57) that individual approach might not have, including (1) validation; (2) normalisation of experience; (3) reduction of isolation; (4) sense of belonging; (5) enhanced self-esteem.

The PICC is conducted within two to three hours each session and facilitated by one leading facilitator and three assistant facilitators. It has four modules to delivered each month consecutively. The control arm will have a three-hour lecture on the same syllabus, however, without SGBI.

Facilitators

As aforementioned, the structured group-based intervention of this study is adopted from Pharmaceutical Services Division, Sarawak State Health Department. Facilitators who have experience conducting at least five times of the intervention will be eligible as facilitators for this study. Apart from training the facilitators to be familiar and consistent in conducting the intervention, the training of the facilitators also includes:

(1) learning how to eliminate concerns and questions the patients come across pertinent to medication adherence with a mnemonic tool “ADHERE” adapted from (58).

- **A**cknowledgement: Acknowledge the concerns of patients.
- **D**iscuss: Discuss with patients on their concerns.
- **H**andle: Handle concerns of patients promptly.
- **E**valuate: Assess patients health literacy and identify possible barriers to adherence.
- **R**ecommend: Suggest an appropriate and feasible solution to the patient.
- **E**mpower: Elicit patients’ willingness to adhere to medications for the long term.

(2) learning what are the Dos and Don’ts when communicating with participants with guidelines (59):

- Adopt a friendly attitude and not a business-like attitude
- Avoid medical jargon
- Use short sentences
- Give explicit instruction and repeat the instructions
- Give specific and detailed information
- Ensure the patients understand by asking them to repeat what had been said

(3) learning patient-centred communication as advocated by (60). It encourages the facilitators to be active listeners and encourage them to think, understand the problems about medication adherence they face and decide to act. It also involves nonverbal communication skills such as nodding and making eye contact to show genuine interest and concern on participants' issues.

To ensure the consistency and correctness of facilitators in conducting the intervention according to the intervention content and applying the communication skills learned, three sessions of the interventions before the actual study will be observed and assessed by the researchers on their performance in terms of coverage of all learning topics, consistency in conducting the intervention, communication with participants and responsiveness to participants' concerns. Besides, the facilitators will also be asked to evaluate their performance on the same aspects. All the aspects mentioned above are required to achieve 90%-100% to qualify as facilitators for this study.

As a whole, each session will require one (1) main facilitators and three (3) assistant facilitators to facilitate the program. The number of participants for each structured group-based intervention session is fixed between 6 to 10 participants. Notably, all the facilitators are the pharmacists who serve under the Pharmaceutical Services Division of the Sarawak State Health Department. The contents of it are depicted in Table 1:

Table 1: Contents of structured PICC programme

MODUL1: INTRODUCTION TO DIABETES

Number of participants: 10 people (minimum)
Objective:

1. Create a support group that helps increase patients' self-motivation in controlling diabetes
2. Recognize and understand diabetes
3. Share the information learned among the participants

Duration	Objective	Activity	Person in-charge	Materials	Procedure
10 minutes	Registration	-	-	• Consent form • Patient • Patient's Information record PICC • myPICC Activity Book	• Write the name on the card (name card) • Distribute consent forms (2 copies) to participants, one copy PF keep, one copy participants, keep • Distribute "PICC Participant Information Record" & "MyPICC Activity Book" to participants • Ask them to fill in demographic data in both books
5 minutes	Briefing PICC	Lecture	Head facilitator	-	• Information about PICC (objective, etc.)

30 minutes	Clinical impact monitoring	Health screening	Medical team	• Health screening kit • Outsource medical team (MA / Nurse / etc.) to help do the health screening • Set up counters to do the health screening	• Explain to participants why we need to do a health screening, what are the things or parameters we are going to measure • The medical team will conduct the following health screenings: • Body Mass Index (BMI) • Blood sugar levels (fasting blood sugar and HbA1c) • Blood pressure level
15 minutes	Ice-breaking	Group activity	Head facilitator	• Cards for name tags	• Participants are divided into groups (maximum five groups) • Each group will be given a card for participants to write their names. • The facilitator will start the ice-breaking session by asking questions: 1. Name 2. Origin 3. Who do you live with (alone / family or with non-family) 4. o History of diabetes
25 minutes	Participants' understanding of diabetes	Brainstorming & Clustering	Facilitator	• Card • Pen marker • Large paper (if any) • Sellotape	• The facilitator gives out one card and one pen to 2 participants (2 participants share one card and one pen, discuss) • The facilitator asks some questions: o Participants' perceptions of diabetes o Factors/causes of getting diabetes

					o Expectations or plans of participants when joining PICC • Participants' answers are recorded on the card. • Give participants 1 minute to write down the answer/idea on the card • After that, each facilitator arranges the ideas (clustering) by category/problem on Large paper or whiteboard or wall with stickers (sellotape) • The facilitator rectifies the "expectations or plans." • Perceptions, factors, rectify later after the module 1 lecture
20 minutes	Module 1: Introduction to Diabetes	Lecture	Facilitator	• Module 1 Slides: Introduction to Diabetes • myPICC Activity Book • Other teaching aids	• Briefing and discussion sessions conducted by the facilitator using Module 1: Introduction to Diabetes (slides or checklists) • The facilitator guides the participants to complete the activities for Module 1 in the myPICC Activity Book. • Assist the participants in doing the activities in the MyPICC Activity Book after almost every slide. (page 4 – 7) • The facilitator should also comment on the participants 'understanding of diabetes based on the ideas on the cards that have been clustered.

					• Representatives of participants from each group may be asked to provide additional comments.
10 minutes	Module 1: Introduction to Diabetes	Group work	Facilitator	• Module 1 Slides: Introduction to Diabetes • myPICC Activity Book	• The facilitator arranges the appropriate place as: 1. Blood vessels (road) 2. Cell (home) • The facilitator identifies the role of the participant in the role-play session: 1. Glucose (passenger) – 8 participants 2. Insulin (car) – 2 participants • Perform role-play activities for two situations: normal individuals & diabetics.
5 minutes	Conclusion for session 1	Lecture	Facilitator	• Module 1 Slides: Introduction to Diabetes • myPICC Activity Book	• Record the date of session 2 in myPICC Activity Book • The facilitator reminded the participants to bring their medicine in session 2.

5 minutes	Participant comprehension test	Pop quiz	Facilitator	• myPICC Activity Book	• Each participant is asked to complete a quiz question (page 8) included in the myPICC Activity Book • The facilitator will check the answers given. • Scores obtained will be recorded on page 2 MyPICC Activity Book & Page 2 Participant Information Record book.

MODULE 2: TAKING ANTIDIABETES MEDICINES

Number of participants: 10 people (minimum)
Target group: PICC participants
Objective:
1. Recognize and understand the indications of DM Medication
2. Explain the concept of 5B in taking DM medication
3. Share the information learned among the participants

Duration	Objective	Activity	Person in-charge	Materials	Procedure
30 minutes	Clinical impact monitoring	Health screening	Medical team	• Health screening kit • Outsource the medical team (MA / Nurse / etc.) to help do the health screening	• The medical team will conduct the following health screenings: 1. Body Mass Index (BMI) 2. Fasting blood sugar (fasting blood sugar) 3. Blood pressure level

				• Set up counters to do the health screening	
15 minutes	Recap for session 1	Generate ideas	Facilitator	• Cards & Pens	• The facilitator obtains feedback from participants on session 1. • Optional: Ask participants/patients to save the book (cannot refer to the book for answers) • 2 – 3 participants (patients) are given 1 card & 1 pen • After that, the facilitator asks questions: 1. How does diabetes occur? 2. What causes diabetes? 3. What is the target sugar level for diabetics? • Patients are given 1 minute to write the answer on the card. • Cards will be collected and clustered on a Large paper/wall/whiteboard. • The facilitator will comment based on the participants' answers.
10 minutes	Participants' understanding of diabetes medication intake	Brainstorming	Facilitator	• Card • Pen marker • Mahjong paper (if any) • Sellotape	• The facilitator gives out one card and one pen to 2 participants (2 participants share one card and one pen, discuss) • The facilitator asks some questions: 1. How do you take diabetes medication? (before, during or after meals)

					2. Where do you store diabetes medicine? • Participants' answers are recorded on the card. • Give participants 1 minute to write down the answer/idea on the card • After that, each facilitator arranges ideas (clustering) according to categories/answers on Large paper or whiteboard or wall with stickers (sellotape) • Rectify later after the module 2 talks
30 minutes	Module 2: Antidiabetic Medication Management and conclusions for session 2	Lecture	Facilitator	• Module 2 Slide: Taking Antidiabetic Medications • myPICC Activity Book • Other teaching aids	• Briefing and discussion sessions conducted by the facilitator using Module 2: Taking Diabetes Medication (slides or checklists) • The facilitator guides the participants to complete the activities for Module 2 in the myPICC Activity Book. • Assist the participants in doing the activities in the MyPICC Activity Book after almost every slide. (pages 10 – 15) • The facilitator should also comment on the participants' understanding of taking diabetes medication based on the ideas on the cards that have been clustered. • Representatives of participants from each group may be asked to provide additional comments. • Optional: Brainstorming & clustering for factors causing hyperglycemia

					and hypoglycemia can be done. • Dates for session three will be stated in the myPICC Activity Book.
5 minutes	Participant comprehension test	Pop quiz	Facilitator	• myPICC Activity Book	• Each participant is asked to complete the quiz (page 16) included in the myPICC Activity Book • The facilitator will check the answers given. • Scores obtained will be recorded on page 2 MyPICC Activity Book & Page 2 Participant Information Record book.

MODULE 3: COMPLICATIONS OF DIABETES

Number of participants: 10 people (minimum)
Target group: PICC participants
Objective:
1. Recognize and understand the complications of diabetes
2. How to prevent and control the complications of diabetes
3. Share the information learned among the participants

Duration	Objective	Activity	Person in-charge	Materials	Procedure

30 minutes	Clinical impact monitoring	Health screening	Medical team	• Health screening kit • Outsource the medical team (MA / Nurse / etc.) to help do the health screening • Set up counters to do the health screening	• The medical team will conduct the following health screenings: 1. Body Mass Index (BMI) 2. Fasting blood sugar (fasting blood sugar) 3. Blood pressure level
15 minutes	Recap for session 2	Generate ideas	Facilitator	• Card	• The facilitator gets feedback from the participants about session 2. • Optional: Ask participants/patients to save the book (cannot refer to the book for answers) • 2 – 3 participants (patients) are given 1 card & 1 pen • The facilitator asks questions: 1. Types of diabetes medications 2. Time of insulin intake 3. Symptoms of hypoglycemia and hyperglycemia • Patients are given 1 minute to write the answer on the card. • Cards will be collected and clustered on a Large paper/wall/whiteboard. • The facilitator will comment based on the participants' answers.
10 minutes	Participants' understanding of the complications of diabetes	Brainstormi ng	Facilitator	• Card • Pen marker • Mahjong paper (if any) • Sellotape	• The facilitator gives out one card and one pen to 2 participants (2 participants share one card and one pen, discuss) • The facilitator asks some questions: 1. Why do complications of diabetes occur? 2. What are the common

					complications of diabetes you see in people with diabetes? • Participants' answers are recorded on the card. • Give participants 1 minute to write down the answers/ideas on the card • After that, each Facilitator arranges ideas (clustering) by category/answer on Large paper or whiteboard or wall with stickers (sellotape) • Rectify later after the module 3 Lecture
30 minutes	Module 3: Diabetes Complications: Description and conclusions for session 3	Lecture	Ketua Sesi / Facilitator	• Module 3 Slide: Complications of Diabetes • myPICC Activity Book • Other teaching aids	• Briefing and discussion sessions conducted by the facilitator with the help of Module 3: Diabetes Complications (slides or checklists) • The facilitator guides the participants to complete the activities for Module 3 in the myPICC Activity Book. • Assist the participants in doing the activities in the MyPICC Activity Book after almost every slide. (pages 18 – 20) • Emphasise the "information" on foot care on page 20 in the MyPICC Activity Book. (not in the slide) • The facilitator should also comment on the participants' understanding of the complications of diabetes based on the ideas on the cards that have been clustered. • Representatives of participants from each group may be asked to provide

					additional comments. • The date for session 4 will be stated in the myPICC Activity Book.
5 minutes	Participant comprehension test	Pop quiz	Facilitator	• myPICC Activity Book	• Each participant is asked to complete a quiz question (page 21) included in the myPICC Activity Book. • The facilitator will check the answers given. • Scores obtained will be recorded on page 2 MyPICC Activity Book & Page 2 Participant Information Record book.

MODULE 4: PRACTICE A HEALTHY LIFESTYLE

Number of participants: 10 people (minimum)
Target group: PICC participants
Objective:
1. Provide exposure to the diet and healthy lifestyle of diabetics.
2. Share the information learned among the participants.

Duration	Objective	Activity	Person in-charge	Materials	Procedure

30 minutes	Clinical impact monitoring	Health screening	Medical team	• Health screening kit • Outsource the medical team (MA / Nurse / etc.) to help do the health screening • Set up counters to do the health screening	• The medical team will conduct the following health screenings: 1. Body Mass Index (BMI) 2. Fasting blood sugar (HbA1c) 3. Blood pressure level
20 minutes	Morning exercise	Aerobic	Physiot herapist	• Music	• Each participant will participate in an exercise led by an aerobics instructor.
5 minutes	Recap for session 3	Generate ideas	Facilitator	• Card	• The facilitator gets feedback from the participants about session 3. • 2 – 3 participants (patients) are given 1 card & 1 pen • The facilitator asks questions: 1. How to reduce the risk of getting diabetes complications? • Patients are given 1 minute to write the answer on the card. • Cards will be collected and clustered on a Large paper/wall/whiteboard. • The facilitator will comment based on the participants' answers.
10 minutes	Healthy lifestyle	Lecture (Slide no. 36 – 40)	Physiothera pist	• Module 4 Slides: • Practice healthy lifestyle • myPICC Activity Book	• Briefing and discussion sessions conducted by physiotherapists using Module 4: Practicing a Healthy Lifestyle (slides or checklists) • Participants complete the activities for Module 4 in the myPICC Activity Book. (pages 23 – 24)

35 minutes	Diet for diabetics	Lecture (Slide no. 41 – 45)	Dietician	• Module 4 Slides: Practicing a Healthy Lifestyle • Teaching aids (example: bowl, plate or spoon to measure the quantity of food) • myPICC Activity Book	• Information sessions and discussions conducted by nutrition science officers using Module 4: Practicing a Healthy Lifestyle (slides or checklists) • The facilitator guides the participants to complete the activities for Module 4 in the myPICC Activity Book. (page 24 – 26) • Demonstrations are shown to reinforce participants 'understanding.
15 minutes	PICC summary	Generate ideas	Facilitator	• Card & pen • Large paper • Adhesive tape	• Participants will be divided into small groups. • Each group will be given 3 pieces of cards, and the answer is written on the card. • The facilitator will ask questions: 1. What causes diabetes? 2. How to control diabetes? 3. What is the targeted sugar level for diabetics? • Cards will be collected, and the facilitator will do clustering. • The facilitator will comment on the answers from the participants. • The facilitator will make a summary of the PICC and the performance of the participants throughout participating in the PICC.

5 minutes	Participant comprehension test	Pop quiz	Facilitator	• myPICC Activity Book	• Each participant is asked to complete the quiz questions included in myPICC Activity Book (page 27) • The answers given will be checked by the facilitator. • The marks obtained will be recorded in the PICC Participant Information Record and MyPICC Activity Book.
5 minutes	PICC Program Feedback	Customer satisfaction survey	Facilitator	• Google Form	• Each participant is asked to complete a customer satisfaction survey as in the link. (page 28 MyPICC Activity Book)
10 minutes	Certificate of Participation Presentation Session	-	-	• Certificate	• Certificate of participation is given to all participants who successfully attend 3 of the 4 sessions of the PICC program.

Content of Control Group

Participants who are assigned to the control group will be given a talk using PICC contains in session, however, without exercises and group-based intervention. Baseline HbA1C will be collected on the date of the talks, while an appointment given in December for the follow-up HbA1C. After that, they will be dismissed and having usual care provided by the health clinic as before without any changes.

Study Timeline and Procedure

The researchers of this study will begin to screen and recruit respondents between 1st August to 31st August 2021. The intervention will be from 1st to 30th September 2021 for all facilities. The post-1-month measurement of HbA1C will be carried out from 1st to 31 October 2021 subsequently by monthly for until the fourth session complete in December. The study timeline is illustrated as in Figure 3 and the study procedure is illustrated in Figure 1.

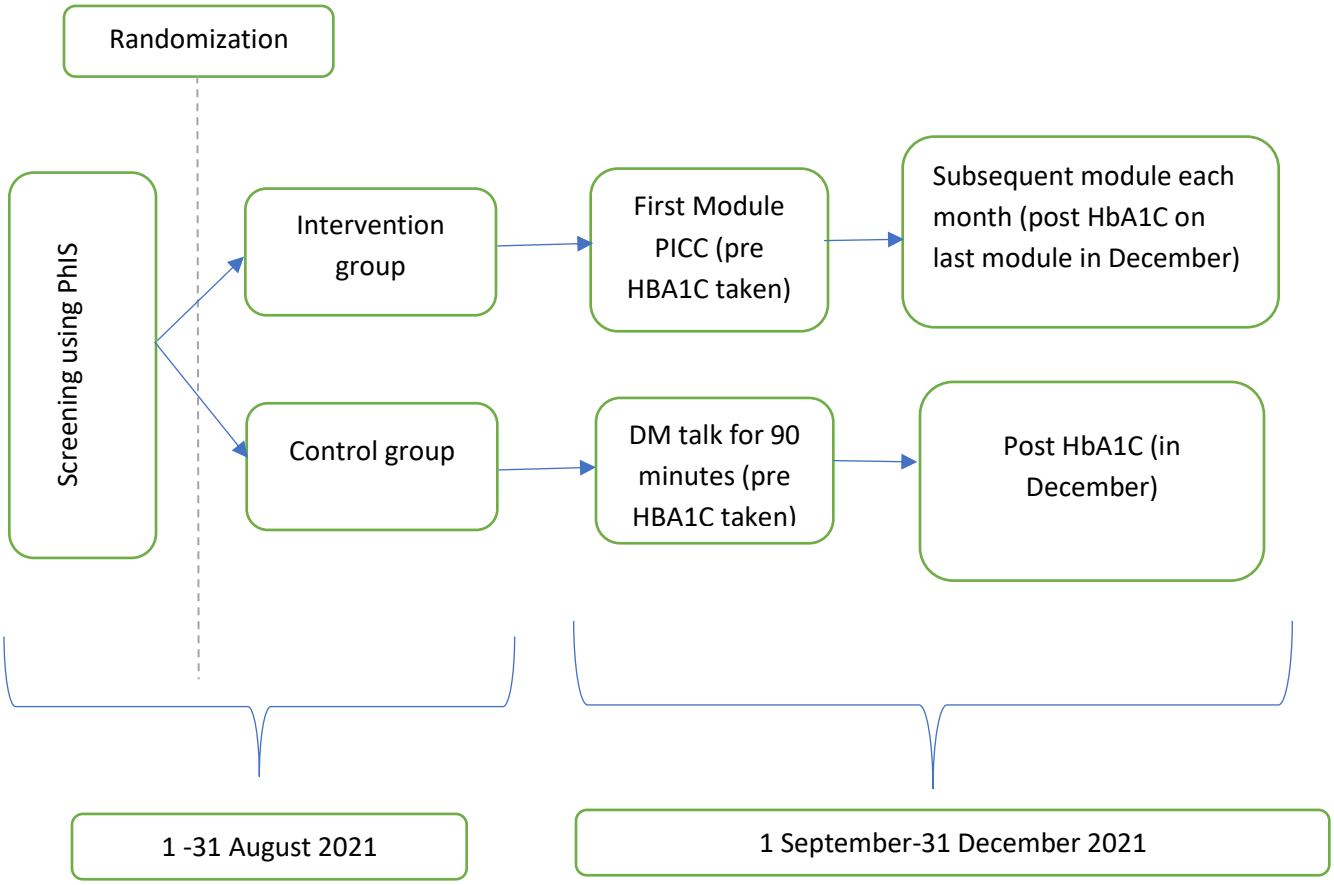


Figure 3: Study timeline

Case report form (CRF)

All the items in the case report form are originally in Malaysia national language, which is Bahasa Malaysia. There are two CRF which are MyPICC Activity Book that is for participants to fill the quizzes on each module, and the Record book PICC that contains patients details, HbA1C, marks for quizzes, medication history, pharmaceutical care issues and referral to other facilities.

Treatment Fidelity

Treatment fidelity of the SGBI will be evaluated using the concept and strategies developed by the Treatment Fidelity Workgroup of the National Institutes of Health Behavior Change Consortium (61). The framework of treatment fidelity strategies for this study is depicted in Table 2:

Table 2: Framework of treatment fidelity strategies

Components	Goal	Strategies
Study design	Ensure the same treatment dose within conditions and equivalent dose across conditions.	(1) SGBI is designed to be completed within four sessions. (2) The use intervention manual will ensure all facilitators consistently conduct the intervention. (3) Observation on a mock intervention conducted by involved facilitators before researchers will do the actual study to assess the consistency and appropriateness in conducting the intervention. Feedback will be given to the facilitators by observers after the observation. The facilitators will also discuss the issues faced during the intervention with the researchers. (4) All facilitators must adhere to the time allocated for each activity throughout the intervention.
	Plan for implementation setbacks.	Have extra four qualified and trained facilitators in case of unavailability of the involved facilitators.
Provider training	Standardise training.	All the qualified and involved facilitators, together with four backup facilitators, will be trained to ensure consistency in conducting the intervention. All sessions of intervention will be observed while to ensure consistency and performance of the involved facilitators.
	Ensure provider skill acquisition.	A scoring scale to assess the qualification and consistency of facilitators in conducting the intervention will be practised.

	Minimise “drift” in provider skills.	During the actual study, researchers will still observe the intervention conducted by facilitators and will be video recorded to ensure the consistency of the intervention. Should the researcher observe less than 90% of consistency compared to training sessions, the reasons that cause the inconsistency will be investigated and reported.
	Accommodate provider differences.	All the facilitators are pharmacists who work in Pharmaceutical Services Division, Sarawak State Health Department. Hence, the facilitators have a similar knowledge background and are considered experts related to the study.
Treatment delivery	Control for provider differences.	Facilitators having a similar background and having same training at the same time
	Reduce differences within treatment.	Scripted intervention protocol is available and used by facilitators
	Ensure adherence to the treatment protocol.	During the actual study, researchers will still observe the intervention conducted by facilitators and will be video recorded to ensure the consistency of the intervention. Should the researcher observe less than 90% of consistency compared to training sessions, the reasons that cause the inconsistency will be investigated and reported.
	Minimise contamination between conditions	The patient allocated randomly while the researcher blinded throughout the trial.
	Ensure participant comprehension.	(1) The participant understanding of the message will be evaluated with the scales developed to measure the intervention's impact on psychosocial variables of participants. Comparison between the intervention group and

Treatment receipt		control group will show whether the improvement in the psychosocial variables is due to chance or is because of the intervention. (2) Qualitative interview after the intervention will enable the researchers to know how the intervention impact their medication-taking behaviour.
	Ensure participant ability to use cognitive skills.	(1) Conduct structured interviews with participants; (2) Facilitators work with participants until they can demonstrate correct medication-taking skills. (3) Hypothetical situations that participants may face in real life will be addressed during group discussion and sharing their reasons for nonadherence and the method they will adopt to overcome the problem.
	Ensure participant ability to perform behaviourally skills.	Facilitators work with participants until they can demonstrate correct medication-taking skills.
Enactment of treatment skills	Ensure participant use of cognitive skills.	Quizzes and a workbook will navigate the participant to comprehend the medication-taking skills.
	Ensure participant use of behavioural skills	HBA1c will be measured on the first and the last session of intervention to ensure the messages conveyed through the intervention are translated into action and such action is maintained.

Outcome measurement

Primary outcome:

HbA1C will be the primary outcome. We will collect this by using a point of care test. Data on glycaemic control will be collected from patient records while demographic details, comorbidities, duration and diabetes complications assessed by using a CRF once participants allocated to the treatment or control group. Facilitators will conduct the point of care before starting the module on the day of the program. Thus, the facilitators are not blinded.

Secondary outcome:

Knowledge and understanding of DM medication management will be evaluated by using the quizzes in the PICC program. The quiz will be evaluated in-situ thus allowing the facilitator to rectify patient's misconception. After the programs ends, the marks of the quiz will be recorded in the CRF. Thus, the facilitators are not blinded.

Statistical Analysis Plan

Data will be computed by using SPSS. The case report form only collects descriptive data which the content validity will be examined before the actual study through three experts' opinions. Differences between groups at baseline and assess the differences of DM knowledge and HbA1c in the intervention and control groups will be analysed using t-test and chi-square test. We will do an intention-to-treat analysis that includes all participants. In order to examine relationships between data, we will use Pearson's or Spearman rho.

Ethical Consideration

All the data are restricted to the principal investigators and solely used for research purposes. The study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and the Malaysian Good Clinical Practice Guideline. This trial will be registered with the Medical

Research and Ethics Committee (MREC), National Institutes of Health Malaysia, before the actual study. Besides, it will be registered with ClinicalTrials.gov following the approval from MREC.

Informed Consent/Assent Process

The informed consent forms will be first given, and the purpose of the study will be explained to the respondent to obtain permission to participate in the study. They will be informed that their participation is voluntary, and they have full right to stop or refused to continue the study at any point of the survey. No penalty or benefits would be given once they stopped or completed the study. All the information given is strictly for research purposes and accessible by principle and co-investigators only. Participants would be informed through a phone call if there were new information relevant to the consent.

Risk and benefit to study participants

As stated in the literature above, there are no severe side effects known to be caused by the PICC programmed. The study procedures are all routine procedures for the group based intervention studied. There is thus a minimal risk for subjects.

This study does not present any direct benefit to the participants. However, the study does provide a better understanding of the disease/condition studied.

Risk-Benefit Assessment

As stated above, there is minimal risk from the investigational product and study procedures. Study findings shall potentially significantly improve treatment outcomes. The expected benefit outweighs the minimal risk to subjects, and thus this study should be supported. If any injuries do occur due to participating in the study, treatment for such injuries shall be provided or paid for by the sponsor.

Privacy and Confidentiality

All participant information will be treated as strictly confidential. Participant have access to their personal information, however not study data. Personal information will be coded to ensure the confidentiality of the participants, and no individuals will be identifiable in any research material, reports or publications. No information collected will be shown to anyone apart from the research team. Data from the study will be stored securely in locked cabinets, and electronic data will be kept on password-protected drives accessible only by the research team. Permission to share information with appropriate health professionals will be sought if health concerns arise for participants.

The dignity and privacy of the participants are always respected and upheld by the researchers of this study as both are the core elements of research ethics (62). Not only the participants will be explained about their rights throughout the study as mentioned above, but they also will be informed that they have the right to decide how much information which is required by this study to disclose. Such information includes their physical status, health, social network, thoughts and feelings.

Nevertheless, all the participants' names will be kept on a password-protected database and linked only with a study identification number for this research. The identification number instead of respondents' identifiers will be used on subject datasheets. All data will be entered into a computer that is password protected. On completion of the study, data in the computer will be copied to CDs, and the data in the computer will be erased. The CDs is password-protected, and any hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after completing the study. The CDs and data will be destroyed after that period of storage. Respondents will not be informed about the study's exaggerated data individually, but this study's findings will be published. Subjects are given access to their personal information and study data.

Conflict of interest

All the investigators declare that they have no conflict of interest. Notwithstanding, the principal investigator will take the responsibility to report any conflict of interest that emerges during the study.

Publication Policy

No personal information will be disclosed, and subjects will not be identified when the findings are published.

Termination of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the Investigator, the Sponsor and the Institutional Review Board (IRB), as appropriate. If the study is prematurely terminated or suspended, the Investigator will promptly inform the IRB and provide the reason(s) for the termination or suspension. Circumstances that may warrant termination or suspension include, but are not limited to:

• Determination of unexpected, significant, or unacceptable risk to participants

• Demonstration of efficacy that would warrant stopping

• Insufficient compliance to protocol requirements

• Data that are not sufficiently complete or evaluable

• Determination of futility

The study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the Sponsor and the IRB.

The sponsor may decide to terminate the study at any time. Subjects will be informed if the study is terminated, and follow-up visits will be arranged if needed.

Part III: Qualitative Survey on PICC Program

Study Design

The qualitative interviews with patients with PICC will be semi-structured, audio-recorded, transcribed and thematically analysed using Excel to identify outcomes and determine the themes described. Ten selected participants conducted one month after the intervention and in-depth interviews with two main facilitators and two managerial officers in charge of the Program 12 months after the intervention. We will explain to all participants the study's objective and be given informed consent before the interviews. The literature review and patient interviews will be combined and prioritised to determine what the most important outcomes are in PICC to patients.

We conduct this study at the study site of each division. Ten participants were purposively sampled to cover a maximum variation of sampling based on the following criteria: (1) able to speak Malay or English; (2) had a written diagnosis of T2DM for at least one year; and (3) had no cognitive or hearing impairments.

An in-depth interview was chosen as the method for data collection as it allowed the researchers to explore participants' personal experiences. A semi-structured interview guide was developed with open-ended and some probing questions were asked to clarify specific issues raised by the participants. Pilot interviews were carried out first in the presence of a senior qualitative researcher to ensure the researcher's interviewer technique was appropriate and to test the protocol guide. After the first two interviews, the protocol guide was revised.

The research questions addressed are:

− RQ1: How did this program help you in improving your medication adherence?

− RQ2: What is(are) the weakness(es) of the program, and what could be done to improve it?

− RQ3: Is there anything else you would like to share with me about the program's impact on your medication-taking behaviour or any suggestions to improve the Program?

In terms of process evaluation purposes, RQ1 is a positive experience about the impact of the program and RQs 2 is a negative case/experience and suggestions, and 3 is a closing question.

All of the interviews took place in a private room at the clinic and were recorded with an audiotape recorder. The interviews were conducted either in Malay or English and lasted for about 35–50 minutes. A basic demographic profile was obtained before each interview. The audio recording will be anonymous, and there will be no mention of personal identifying information such as names, IC numbers, etc., during the interview. The audio recording is for transcription purposes and will not be copied/sent to any other individual or used for any other purpose. After transcription, the audio recording will be disposed of securely.

We conduct the data analysis simultaneously with the data collection. At the end of each interview, the interviewer summarises what was understood by the participants and asked them to check for any missed or inaccurate information. After the interview session ended, a debriefing session held where the researcher wrote down a summary and reflections. The interview then transcribed and compared with the audio recording to ensure its accuracy. The

text then transferred to Excel for analysis. Subsequently, the researcher heard the audio recording and read the transcript to understand the whole data before beginning to code the text.

Thematic analysis was applied, and coding was done in several steps. Initially, a descriptive level of coding was done to a segment of text, which was either a few phrases, one single or several sentences, or paragraphs. The research team then discussed the code labels, and some parts of the text were re-coded again. After several transcripts, an interpretative level of coding was performed; later, the codes with similar meanings were grouped. This process continued till subthemes and themes were developed. After the sixth interview, the preliminary themes and subthemes were reviewed and discussed among the research team. Some codes were re-categorized, and the subthemes, as well as themes, were further redefined. The data collection concluded at the tenth interview as the data reached a saturation point where no new themes emerged.

Analysis Plan

The qualitative data collected through the semi-structured interview, the constant comparative method for qualitative analysis with the assistance of ATLAS.ti, will be used to identify the themes related to the questions.

Ethical Consideration

All the data are restricted to the principal investigators and solely used for research purposes. The study will be conducted in compliance with ethical principles outlined in the Declaration of Helsinki and the Malaysian Good Clinical Practice Guideline. This qualitative survey will be registered with the Medical Research and Ethics Committee (MREC), National Institutes of Health Malaysia, before the actual study.

Informed Consent/Assent Process

The informed consent forms will be first given, and the purpose of the study will be explained to the respondent to obtain permission to participate in the study. They will be informed that their participation is voluntary, and they have full right to stop or refused to continue the study at any point of the survey. No penalty or benefits would be given once they stopped or completed the study. All the information given is strictly for research purposes and accessible by principle and co-investigators only. Participants would be informed through a phone call if there were new information relevant to the consent.

Privacy and Confidentiality

The dignity and privacy of the participants are always respected and upheld by the researchers of this study as both are the core elements of research ethics (62). Not only the participants will be explained about their rights throughout the study as mentioned above, but they also will be informed that they have the right to decide how much information which is required by this study to disclose. Such information includes their physical status, health, social network, thoughts and feelings.

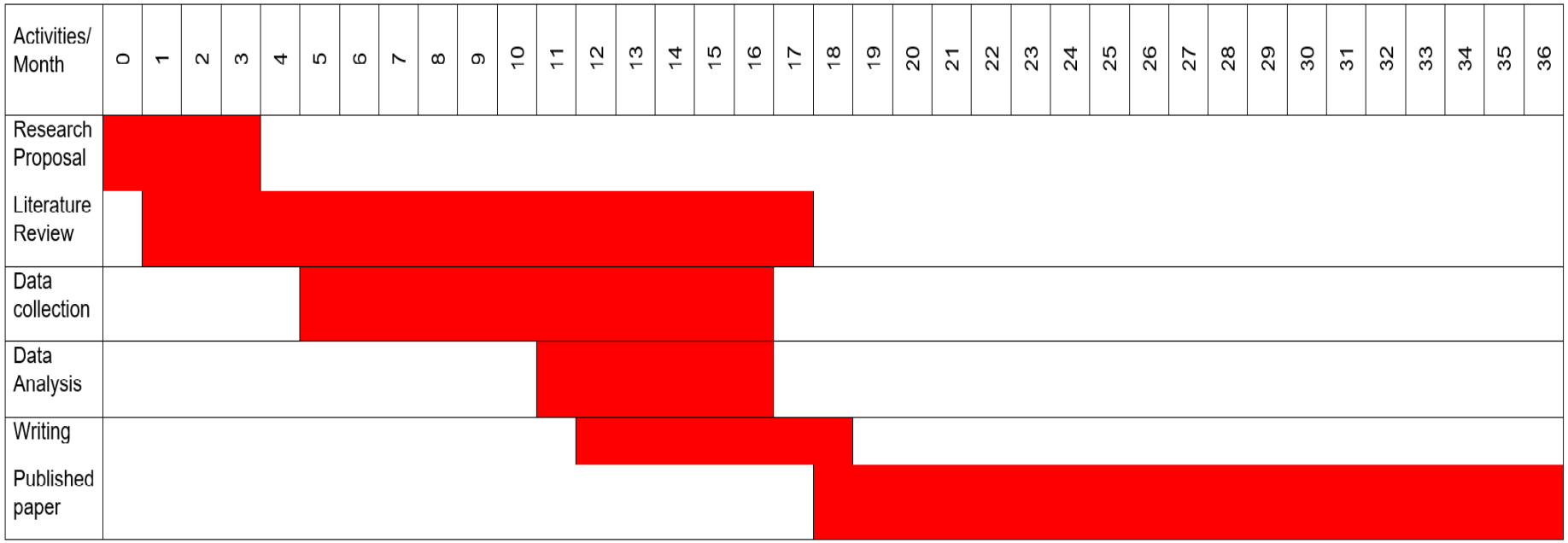
Nevertheless, all the participants' names will be kept on a password-protected database and linked only with a study identification number for this research. The identification number instead of respondents' identifiers will be used on subject datasheets. All data will be entered into a computer that is password protected. On completion of the study, data in the computer will be copied to CDs with password-protected, and the data in the computer will be erased. CDs and any hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after completing the study. The CDs and data will be destroyed after that period of storage. Respondents will not be informed about the study's exaggerated data individually, but this study's

findings will be published. Subjects are given access to their personal information and study data.

Publication Policy

No personal information will be disclosed, and subjects will not be identified when the findings are published.

6. Gantt Chart



7. Estimated Costs

Items	Quantity	Cost (RM)	Remarks
White A4 Paper	30 Rims (30 x RM10.00)	300.00	To print journal articles, questionnaires and reports.
Printer Toner (HP LaserJet 1300)	Two units (2 x RM300.00)	600.00	To print journals articles and reports.
Flash Drives 4G (Kingston/ Apacer)	Two units (2 x RM100.00)	200.00	To save journal articles. For the preparation of report writing.
Travelling Expenses: - Conducting face-to-face survey and PICC program	-	15, 000.00	-
Enumerators for trials	9 sites (Total payment per enumerator-Rm200)	5,200.00	4 session each, 2 enumerator per session. 26 trained facilitators/enumerators will be involved.
The enumerator for the qualitative survey	12 interviews (RM 200 per interview)	2,400.00	
Translation job	-	500.00	To translate journals (other than English language articles)
Transcriber for qualitative survey	12 transcriptions (RM 100 each)	1200.00	
Publication Proofreading	4 research papers (RM 1000 each)	4,000.00	

Point-of-care test for HbA1C	9 kits for 9 site	4,550.00	
Lancet	52 box (20's)	520.00	
Alcohol swab	4 box (100's)	20.00	
TOTAL (RM)		34,490.00	

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Appendix 1

Data extraction form for Systematic Review

Study design	
Trial characteristics	
Intervention details	
Participant characteristics	
outcome measures	
results	
random sequence generation	
allocation concealment	
blinding of participants and personnel	
blinding of outcome assessment	
incomplete outcome data	
selective reporting	
other bias	

Appendix 2

Data Collection form during the trials

REKOD MAKLUMAT PESERTA
PROGRAM PHARMACY INTEGRATED COMMUNITY CARE (PICC)

Data Demografik

Nama Penuh					
No. KP		No. Telefon		Umur	
Alamat				Bangsa	
				Jantina	
Tinggi (m)		Berat (kg)		BMI (kg/m²)	

Sejarah Pengubatan

Status Kesihatan/Diagnosis Terkini:			
Alahan (jika ada):			
Merokok:		Pengambilan Alkohol:	Mengandung/ Menyusukan:
☐ Ya ☐ Tidak ☐ Telah berhenti** ☐ Perokok Pasif***	** tidak merokok selama 6 bulan atau lebih *** tinggal dengan individu yang merokok	☐ Ya ☐ Tidak ☐ Telah berhenti ☐ Tidak berkenaan	☐ Ya ☐ Tidak ☐ Tidak berkenaan

Rekod Pemeriksaan Kesihatan

Sesi	Sesi 1	Sesi 2	Sesi 3	Sesi 4
Tarikh				
Tekanan darah (mmHg)				
Bacaan paras gula – puasa (mmol/L)				
Bacaan paras gula – rawak (mmol/L)				
Tarikh				
HbA1c (%) (jika ada)				

Markah Med Kuiz

Sesi	Sesi 1	Sesi 2	Sesi 3	Sesi 4
Tarikh				
Markah				

INFORMATION SHEET

Study Title:	Effectiveness of Pharmacy Integrated Community Care (PICC) improving Hemoglobin A1c (HBA1C) and Knowledge in diabetes mellitus (DM) education program
Protocol No.:	
Sponsor:	*Pharmaceutical Service Division, Sarawak State Health Department*
Investigator Name:	*Kamarudin Bin Ahmad*
Investigator Contact No.	*0128789869*

Consumer Information:

Name:	
Telephone No.:	
Address:	
Identity Card Number:	

Introduction

You have been invited to participate in a research study to examine the effectiveness of a group-based intervention in improving knowledge and self-care in diabetes with underlying Type 2 Diabetes Mellitus in the Sarawak State of Malaysia.

The Ministry of Health Malaysia designs an education program for diabetes mellitus under the "Know Your Medicine" campaign. The program called Pharmacy Integrated Community Care (PICC) hopes to improve knowledge and self-care for diabetes mellitus patients. PICC contains four modules that will provide knowledge on diabetes mellitus in an interactive, easy understand and fun program. We are interested in evaluating the effectiveness of the program in order to see its relevance to Malaysian.

This information sheet gives you a detailed description of this study and will help you to decide if you would like to participate. Please read this sheet thoroughly and ask any questions that may occur to you. Participation in this research is voluntary.

This study has been approved by the Medical Research and Ethics Committee of Malaysia.

Q1: What about this study?

PICC is an education program to give knowledge on diabetes mellitus to the patients. It intended to improve self-care knowledge to patients with underlying Type 2 Diabetes Mellitus conducted to whole Malaysia. However, in Sarawak, we interested in conducting it together with this is an experimental study, which aims to examine the effectiveness of PICC. The study is being conducted in the nine Sarawak Division. A minimum of 94 respondents will be participating in this study. Your profile details will be taken with strict confidentiality.

Q2: What will happen when you agree to participate?

Your responsibility:

1. We need you to fast at 10 pm the day before the program to take fasting blood glucose levels. The program will start at 8 am, with a health check-up, and breakfast will be provided.
2. We need you to be punctual in order to run the program smoothly. You do not have to bring anything as all materials will be provided.

Before the program:

If you agree to take part in this study, the researcher will obtain written consent from you. After that, you will be invited to attend a program held at Health Clinic near your area from 1st September 2021 to 31st December 2021. You may choose the date that you prefer to attend, and you are acquired to present on the date that you had chosen. However, any change of your preference before the program must be informed to the investigators. Should there be a change or new information relevant to consent, we will inform you and request consent from you again.

You will be "randomised" into one of the study groups described below. Randomisation means that you are put into a group by chance. A computer program will place you in one of the study groups, similar to flipping a coin. Neither you nor your investigator can choose the group you will be in. Only participants assigned to the intervention group will have to attend a program for four-session with free health check-ups for each session. Participants who are assigned to a controlled group will only have one session, with two free health check-up which is on the day of sign up and the day of the session. Free health check-ups consist of blood pressure, fasting blood glucose and HbA1C.

During the program:

On the day of the program, you will need to register yourself at the outpatient pharmacy department of the health clinic near you that we tell on the phone. After registration, you will be informed about the actual location of the program that you will attend. One of the locations will be the intervention group's venue, while the other one for the controlled group. Participants assigned to the intervention group will attend the PICC program, which will take four-month and each session 2.5 hours. Participants assigned to the controlled group will have 2 hours lecture and spend approximately 30 minutes answering quizzes related to this study.

During the program, we will introduce the content of the education module. You required to:

1. To do basic health check-ups with us
2. Participate in the light activity in the intervention group while in the control group to listen to a lecture.
3. At the end of the program, a short written quiz is given.

After the program:

After four (4) months of the program finished, participants from both groups will be interviewed for approximately 5 minutes through phone call.

During the interview, we ask:

1. Your consent for the recorded interview
2. To share your experience and comment freely will help to improve the program

Q3: Are there any risks?

The module of this study only consists of education that may involve light to minimal physical activities. The program is designed to engage the mind and, in the process, will ease the learning of diabetes mellitus knowledge. Since there is no clinical intervention or invasive procedure involved in this study, thus no risks to your health would arise.

If you are injured by being in this study, treatment is available. Your insurance will be billed for the cost of treatment. The sponsor will pay for any necessary medical costs related to the treatment of your injury due to your taking part in the study and not paid by your insurance or any other payor. If you are injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up your legal rights by signing this form. However, if you think you have a study-related injury, please contact us, and we will assist.

Q4: Are there any benefits?

If you participate in this research, you will have the following benefits: the health check-up is free that consist of blood pressure, fasting blood glucose and HbA1C that we will share with the participants. There may not be any benefit for you, but your participation is likely to help find the answer to the research

question. There may not be any benefit to society at this stage of the research, but future generations are likely to benefit.

The outcome of this study will be used to evaluate the effectiveness of the PICC in improving knowledge in self-care to apply the intervention to a larger population with underlying Type 2 Diabetes Mellitus. However, this study's results will not be informed to you individually as it only aimed to be translated into practical implications.

Q5: What if you do not want to participate, and when can you leave the study?

Your participation in this study is voluntary, and it is entirely your decision. You can choose to leave the study at any time. Having agreed to participate and have signed the informed consent form, if you change your mind, your choice will be respected. However, you should inform the researcher about the reason behind your decision to withdraw. Those that are not consenting to participate as well as withdrawal of consent and with or without continuation of this program will not affect the medical services entitled.

Q6: What if this study terminated?

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the Investigator and Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia, as appropriate. If the study is prematurely terminated or suspended, the Investigator will promptly inform the MREC and provide the reason(s) for the termination or suspension. Circumstances that may warrant termination or suspension include, but are not limited to:

• Determination of unexpected, significant, or unacceptable risk to participants

• Demonstration of efficacy that would warrant stopping

• Insufficient compliance to protocol requirements

• Data that are not sufficiently complete and evaluable

• Determination of futility

The study may resume once concerns about safety, protocol compliance, data quality are addressed and satisfy the MREC. The sponsor may decide to terminate the study at any time. You will be informed if the study is terminated, and follow-up visits will be arranged if needed.

Q7: What is the cost of the study?

You do not need to pay and will not be paid for taking part in this study. This study is sponsored by Pharmaceutical Service Division, Sarawak State Health Department.

Q8: Will the information and your identity remain confidential?

The information that we collect from this research project will be kept confidential. Information about you collected during the research will be put away, and no one but the researchers will see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone except by the study investigators of the Pharmaceutical Service Division, Sarawak State Health Department. On completion of the study, data in the computer will be copied to CDs, and the data in the computer will be erased. The CDs is password-protected, and any hardcopy data will be stored in a locked office of the investigators and maintained for a minimum of three years after completing the study. The CDs and data will be destroyed after that period of storage. The confidentiality of your identification and information will always be protected. Your identification and information will not be used for other purposes or by other parties without your consent.

All the results of this study will be treated in complete confidence to the extent permitted by law. All the data are restricted to the principal investigators and solely used for research purposes and publication. The participant will be informed after the data is published.

Q9: How will my data be used?

All your information obtained in this study will be kept and handled confidentially, under applicable laws and regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect your medical records and study data where appropriate and necessary

\Q10: What if you have more questions or do not understand something?

If you have any questions about the study or if you think you have a study-related injury and you want information about this study, please contact :

Mr Kamarudin Bin Ahmad

at 0128789869 or kamarudin_a@moh.gov.my

If you have any questions about your rights as a participant in this study, please contact The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-3362 8407/8205/8888.

INFORMED CONSENT FORM

PARTICIPANT COPY

STUDY TITLE

Effectiveness of Pharmacy Integrated Community Care (PICC) improving Hemoglobin A1c (HBA1C) and Knowledge in diabetes mellitus (DM) education program

(Protocol Number:)

CERTIFICATION BY INVESTIGATOR

I, being the researcher, confirm that I have fully explained the nature, purpose and reasonably foreseeable risks of taking part in this study to the participants or legal representative. He/she has read and kept a copy of the Information Sheet and signed the Informed Consent Form. He/she has freely agreed to participate in the study.

Signature: I.C number:

Name: Date:

CONSENT BY PARTICIPANT

I have read and understood the Information Sheet about this research and have been given a chance to ask any questions. I understand and accept the answers that have been given.

I confirm that I have been given enough time to think about and have freely agreed to take part in this research and know that I can at any time, ask for more information from the pharmacist and doctor, and cease to participate in the research without affecting my health status in any way.

I also understand that should I decide to stop taking part in this study, I do not need to explain why. In this case, I must report the details to the pharmacist.

Finally, I agree to participate in the research and to follow the instructions I am given closely. I have received a copy of the Information Sheet and Informed Consent Form.

Signature: I.C number:

Name: Date:

IF REQUIRED IMPARTIAL WITNESS

Signature: I.C number:

Name: Date:

INFORMED CONSENT FORM

FACILITY COPY

STUDY TITLE

Effectiveness of Pharmacy Integrated Community Care (PICC) improving Hemoglobin A1c (HBA1C) and Knowledge in diabetes mellitus (DM) education program

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